

In the United States Court of Federal Claims

No. 98-817 V
(Filed March 3, 2008)

ENRIQUE M. ANDREU, a minor)
child by his parents and natural)
guardians, ENRIQUE C. ANDREU)
and SONIA C. ANDREU,)
Petitioners,)
v.)
)
SECRETARY OF THE)
DEPARTMENT OF HEALTH AND)
HUMAN SERVICES,)
Respondent.)

ORDER^{1/}

Petitioners, Enrique C. Andreu and Sonia C. Andreu seek review and reversal of the Special Master's Decision denying their petition for compensation under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-1 to 34 ("Vaccine Act"). Petitioners assert that the genesis of their son Enrique's seizures, which initially occurred on November 1, 1995, was a diphtheria, tetanus, and whole-cell pertussis ("DPT") vaccination he was administered on October 31, 1995.

The respondent, Secretary of the Department of Health and Human Services, requests that the Special Master's Decision denying compensation be sustained.

With respect to the function of this court, the Vaccine Act provides:

^{1/} Petitioners have 14 days to request redaction of any material "that includes medical files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the entire decision, while not published, will be available on the court's website. 42 U.S.C. § 300aa-12(d)(4)(B).

(2) Upon the filing of a motion [to review a special master's decision], the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

. . . .

42 U.S.C. § 300aa-12(e)(2).

The Vaccine Act establishes the standard for recovery of compensation as follows:

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition

42 U.S.C. § 300aa-13(a).

Of relevance to this case, 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) provides that for recovery of compensation, the petitioners must have demonstrated by a preponderance of the evidence on the record as a whole, that Enrique “sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A) . . .”^{2/}

The relevant record on which the causation decision was rendered in this matter consists of medical records and literature; testimony at an August 27, 1999 “onset” hearing before Special Master Abell from witnesses Sonia C. Andreu, Enrique C. Andreu, Eric Andreu, and Jesus A. Gutierrez; pre-hearing affidavits from these witnesses; and testimony at a November 3, 2006 “causation” hearing before Successor Special Master Vowell from petitioners’ expert witness, Dr. Carlo Tornatore and respondent’s expert witness, Dr. Joel Herskowitz.

Based upon this record, Special Master Vowell on August 29, 2007, issued a 41-page decision available on the court’s website (hereinafter cited as “slip op.”) concluding that petitioners “failed to show that Enrique’s seizures were caused by his DPT vaccination on October 31, 1995.”

Petitioners’ Motion for Review takes issue with the successor special master’s conclusion and several aspects of the analysis employed to reach that conclusion.

There is no dispute concerning the facts that Enrique received a whole-cell pertussis DPT vaccination on October 31, 1995, and that he suffered focal seizures commencing on November 1, 1995, which after some stable periods have morphed into serious generalized seizures producing developmental delays. It is agreed by all concerned that whatever caused the seizures commencing on November 1, 1995, is also the cause for all subsequent seizure activity.

^{2/} Subparagraph (A) refers to the Vaccine Injury Table. DPT is listed in this table. *See* 42 U.S.C. § 300aa-14. An injury meeting the relevant criteria in the table is presumed to be caused by the vaccine. 42 U.S.C. § 300aa-11(c)(1)(C)(i). Petitioners initially pleaded that Enrique’s seizures were covered by the table so that causation was presumed, but also plead actual causation. *See* Petition ¶¶ 11, 16, filed October 26, 1998. Petitioners subsequently withdrew their table injury claim and rely on the record to claim actual vaccine causation. *See* Tr. 58 (Nov. 3, 2006).

For the factual background which the expert witnesses were instructed to utilize in reaching their expert opinions, the successor special master embellished the 1999 onset ruling by Special Master Abell with an interpretation that testimony by Enrique's parents was not reliable. This interpretation was added based essentially on a sentence on page 16 of Petitioners' Exhibit 21 (a "baby book") which indicated that Enrique suffered "focal seizing" on November 3, 1995, whereas the seizures were not diagnosed as "focal" until November 11, 1995. Mr. Andreu testified in 1999 before Special Master Abell that the book entry was made on the date listed, November 3, 1995. (Tr. 92 (Aug. 27, 1999).) While the testimony some four years later as to the entry date would appear to be incorrect, the information recorded is likely accurate, given the onset finding of an earlier date, November 1, 1995, and the subsequent "focal" diagnosis. In his oral bench decision on August 27, 1999 (*id.* at 139-40), Special Master Abell noted that if matters in the medical records referring to the parents were considered, he would have found November 8, 1995, to be the supported date for seizures, but, instead, he gave credibility to the testimony of the grandfather, Jesus Gutierrez, who had daytime custody of Enrique, and placed the onset date at November 1, 1995. Except for Mr. Gutierrez, there is no other mention of credibility. When the oral decision was reproduced and filed on October 20, 1999, Special Master Abell added a preface stating:

On 27 August 1999, the Court conducted an onset hearing in Miami, Florida. The Court heard the testimony of several fact witnesses proffered by Petitioners. At the close of the onset hearing the Court issued a bench ruling, noting that the lynchpin for this onset decision was the highly credible testimony of Petitioners' grandfather, Señor Jesus Guiterrez [sic], and secondarily, Enrique's step brother, Eric Daniel Andreu. Petitioners' preponderance burden during the onset hearing would not have been met were it not for the firm integrity and veracity reflected in Señor Guiterrez's [sic] testimony. As a result, I hereby affirm that bench ruling and the conclusions made therein regarding the issue of onset, and incorporate the attached copy herein.

The onset date determination of November 1, 1995 rather than November 8, 1995, was crucial for petitioners' then Table Injury claim as the table requires the manifestation of onset to be within three days after a DPT vaccination. 42 U.S.C. § 300aa-14. With the subsequent withdrawal of the Table Claim the entire onset issue lacks relevance except to the extent it establishes temporal relationship and to the

extent the factual evidence adduced could also be utilized as a part of the basis for subsequent expert opinion as to causation, an issue which was not addressed at the 1999 hearing – “[n]ow, the court understands that this hearing today is exclusively for the purpose of establishing the underlying data on onset.” (Tr. 3 (Aug. 27, 1999).)

The record of the August 27, 1999 hearing does not support the successor special master’s determination in the August 29, 2007 Decision at issue that Special Master Abell made any credibility determination with respect to the then record evidence other than his favorable comments with respect to Mr. Gutierrez’s testimony. Moreover, there is no support for the determination that Special Master Abell made any “findings” beyond his determination as to the onset date for the seizures suffered by Enrique. What the successor special master interpreted as “findings” at Tr. 143-44 (Aug. 27, 1999) are simply observations and speculation by Special Master Abell after he had completed his onset conclusion. These observations are not denominated as “findings” and, *e.g.*, the speculation as to Enrique having a “local reaction” and its extent, at the vaccine administration site (*id.* at 143) is directly contrary to Special Master Abell’s instruction at the opening of the hearing that “we are not taking medical testimony nor is the court going to conclude that there was or was not any medical issue, as such, other than would be specifically exhibited in the records.” (*Id.* at 3.) The embellishment of Special Master Abell’s onset determination, by the successor special master, to add credibility conclusions and findings not expressly set forth therein cannot be sustained. *See Zand v. C.I.R. Serv.*, 143 F.3d 1393, 1399-1400 (11th Cir. 1998). In this circumstance, absent a prior credibility evaluation with respect to Enrique’s parents’ evidence, the special master’s expressed concern as to their credibility, based on a likely accurate entry in a baby book but inaccurate testimony some four years later as to when it was recorded, should be reconsidered. The successor special master had no opportunity to hear the testimony or observe the witnesses and the witness writing the entry was never directly confronted with the apparent conflict in the context of the implications which were contemplated. Cross-examination on this point was truncated by the prior special master hearing the testimony (Tr. 104 (Aug. 27, 1999) and evidence as to seizures on November 3, 1995, became irrelevant with the determination of the even earlier November 1, 1995 seizure onset date.

The special master’s failure to recognize the limited nature of Special Master Abell’s onset hearing and determination had further adverse implications for the presentation of petitioners’ causation case. An order, filed May 1, 2006, reports that

at an unrecorded status conference on April 27, 2006, a deadline was set for petitioners to “file a statement made by Dr. Carlo Tornatore stating that his expert opinion in this matter relied upon the facts established by Special Master Richard Abell in the October 29, 1999 decision regarding onset.” Petitioners complied and filed a statement made by Dr. Tornatore that his opinion did not conflict with the onset decision findings. (Petitioners’ Ex. 26.) Nevertheless, at the causation hearing on November 3, 2006, the special master objected to Dr. Tornatore’s reference to record evidence such as the affidavits filed by Enrique’s parents, and their prior testimony again raising a credibility issue and assigning “findings” status to medical issue observations made by Special Master Abell which were beyond the scope of the onset hearing. While this occurred during testimony addressed to the possibility of establishing a table injury and, therefore, were rendered irrelevant with the withdrawal of the table injury claim, the successor special master carried the issue over to support a determination that Dr. Tornatore’s testimony on causation-in-fact lacked credibility.^{3/} Slip op. at 40.

To show causation in fact, petitioners must show:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) . . . a proximate temporal relationship between vaccination and injury.

^{3/} In the August 29, 2007 Opinion (slip op. at 15-18), Dr. Tornatore’s testimony, in support of a table injury, that Enrique suffered an encephalopathy is unjustly treated with derision. Dr. Tornatore used the term “encephalopathy” in the broader sense employed in the medical community to mean “a disruption in the way the brain is working, an inability to interact with your environment.” (Tr. 51 (Nov. 3, 2006).) This definition was accepted by respondent’s expert, Dr. Herskowitz, who noted that he did not use the Vaccine Table to diagnose encephalopathy. (Tr. 192 (Nov. 3, 2006).) The issue with respect to the existence of a table encephalopathy was the extent of Enrique’s inability to interact with the environment. Dr. Tornatore’s reliance upon record evidence from Enrique’s parents, principally his extensive crying post-vaccination, the diagnosis of encephalopathy by a treating neurologist, Dr. Marcel J. Deray (Petitioners’ Ex. 22) and the accepted medical usage for the term “encephalopathy” was held to be “efforts to contort the facts and the definitions to bring Enrique’s symptoms within the Table” Slip op. at 18, Aug. 29, 2007. While the environment interaction evidence can be ruled not to meet the level a table injury requires, and petitioners were correct to withdraw the table claim, to characterize Dr. Tornatore’s testimony as “evocative of the term ‘hired gun’” (*id.*) is arbitrary and cannot be sustained on review.

Capizzano v. Sec'y of Health and Human Servs., 440 F.3d 1317, 1324 (Fed. Cir. 2006).

Dr. Tornatore's expert report and testimony, standing alone, would meet the *Capizzano* requirements for recovery of compensation. His report and testimony sets forth a medical theory causally connecting the DPT vaccination administered to Enrique on October 31, 1995, to the seizures which had their genesis on November 1, 1995. Both parties' experts, Drs. Tornatore and Herskowitz, agreed as to the biologic plausibility of Dr. Tornatore's medical theory. Slip op. at 29. Clearly, temporal connection was established in that a seizure within 24 hours of vaccine administration would satisfy even the 72-hour requirement for a DPT table injury. *Id.* at 39. Dr. Tornatore's testimony explains his opinion as to the sequence of cause and effect showing that the toxins present in whole-cell pertussis vaccine in bloodstream circulation after vaccine administration can cross into the brain causing behavioral change, such as unusual crying, and, depending on the extent of injury to the brain, seizures. (Tr. 29-33, 73-83 (Nov. 3, 2006).) Dr. Tornatore has excellent medical credentials. Slip op. at 14; *Adams v. Sec'y of Health and Human Servs.*, 76 Fed. Cl. 23, 32-33 (2007).

Beyond the issues as to Dr. Tornatore's credibility related to the onset decision and the table injury testimony which cannot be sustained on review of the record, the successor special master also reached the conclusion that petitioners had not established causation by a preponderance of the evidence based primarily on the fact that Enrique's initial seizures were not accompanied with a fever, *e.g.* were afebrile, and on Dr. Herskowitz's testimony that the "toxin" event postulated by Dr. Tornatore, if it occurred, should be expected to produce greater injury than was present in Enrique's clinical picture. Slip op. at 29, 39. Dr. Herskowitz did not put forth any alternative causation theory for Enrique's seizures, but opined only that they were unrelated to the DPT vaccinations on October 31, 1995. (Tr. 168 (Nov. 3, 2006).) Dr. Herskowitz also has excellent medical credentials, and like Dr. Tornatore, has testified in a number of vaccine cases before this court. Slip op. at 26-27; *Estep v. Sec'y of Health and Human Servs.*, 28 Fed. Cl. 664, 667 (1993); *DeRoche v. Sec'y of Health and Human Servs.*, No. 97-643V, 2002 WL 603087, at *12 n.36 (Fed. Cl. Spec. Mstr., Mar. 28, 2002) ("Dr. Herskowitz has testified on respondent's behalf in approximately 30 vaccine claims and reviewed about 60 cases.").

The successor special master also found an absence of support for DPT causation in the medical records developed by treating physicians. Enrique's treating pediatric neurologist, Trevor J. Resnick, on December 27, 1995, provided a report on his "follow-up" examination on that date stating (in relevant part):

I saw Enrique today in follow-up. He was admitted to Miami Children's Hospital a month ago with a history of left-sided focal seizures involving predominantly arm and characterized by clonic jerking, lasting approximately 15-20 seconds. He had four or five seizures prior to admission. In other respects, he was a product of an uncomplicated delivery and has subsequently normal developmental milestones. His imaging study did not show any correlate of the focal correlates of the seizures, although he did have some ipsilateral atrophy. Nevertheless, since discharge he has continued to demonstrate normal neurodevelopmental progress and is seizure free on phenobarbital. The one consideration was the fact that the seizures did occur in temporal relationship to his DPT immunization, although no other symptomatology such as fever or irritability occurred.

....

ASSESSMENT: Enrique has done really well since last seen. He has had no further seizures and there are no focalities on examination. I indicated to Mr. and Mrs. Andreu that his future immunizations should not include pertussis, but that he could get all other immunizations. I plan to repeat his EEG in five-months time and if normal will discontinue the phenobarbital.

(Petitioners' Ex. 7, pp. 31-32.)

Another treating physician was neurologist Dr. Marcel J. Deray. A discharge summary in Dr. Deray's medical records, dictated on November 2, 1998, stated as follows (in relevant part):

The patient [Enrique] has a history of recurrent seizures associated with cyanosis; however, this was the first time the cyanosis has occurred without a seizure. The mother noticed that the child's lips were blue

yesterday and while sleeping. The mother was concerned secondary to this and called Dr. Deray, and the patient was therefore admitted for evaluation. On further investigation, it seems that the patient's seizure disorder may be secondary to a DPT immunization that was given at 2 months of age.

(Petitioners' Ex. 15, p. 40.)

Dr. Deray subsequently provided a statement, dated December 4, 2001, which reads:

Enrique is a patient I have followed since 11/22/96. He has an encephalopathy and seizures. There has been no neurological cause found for his encephalopathy and no other explanation other than the DPT immunization given to him when he was an infant.

If you should require further information, please feel free to contact this office.

(Petitioners' Ex. 22.)

Dr. Tornatore in his testimony relied upon Dr. Resnick's instructions not to allow pertussis in Enrique's future vaccinations and Dr. Deray's statement as supporting DPT causation for Enrique's seizures. (Slip op. at 24; Tr. 28, 59-62, 72 (Nov. 3, 2006).)

The successor special master concludes that Dr. Tornatore "took statements of treating physicians out of context, and attributed to those physicians opinions on causation that were not fully supported by the record." Slip op. at 40.

In fact, it is reasonable to rely on Dr. Resnick's "no pertussis" instruction as supporting DPT seizure causation. This no-more-vaccine position because of a reaction was so construed in *Kelley v. Sec'y of Health and Human Servs.*, 68 Fed. Cl. 84, 98, 100 (2005). Dr. Herskowitz testified that in his opinion Dr. Resnick was merely being cautious and no causation implications were intended. (Tr. 178 (Nov. 3, 2006).) The successor special master accepts Dr. Herskowitz's interpretation of Dr. Resnick's instruction. Slip op. at 25. Neither Dr. Tornatore nor Dr. Herskowitz

or the successor special master had any contact with Dr. Resnick. All that is in the record in this matter is Dr. Resnick's medical records and, in measuring the evidence to determine preponderance, one has to conclude that an instruction not to allow pertussis in future vaccinations must be placed on the plus side for causation absent further evidence from Dr. Resnick. Dr. Tornatore correctly relied on this medical record for causation support and the conclusion to the contrary based upon speculation as to Dr. Resnick's motivation, cannot be sustained upon review.

With respect to the treating neurologist, Dr. Deray, the successor special master interprets his 2001 statement, quoted above as stopping "[s]hort of an opinion that the DPT vaccine was causal, . . ." Slip op. at 25. However, Dr. Deray's statement is in the nature of a "differential diagnosis" or "differential etiology," which is a standard scientific technique, with widespread acceptance in the medical community, employed to identify the cause of a medical problem by eliminating the likely causes until the most probable is isolated. *See Hocraffer v. Sec'y of Health and Human Servs.*, 63 Fed. Cl. 765, 777 n.15.^{4/} Accordingly, it cannot be correctly concluded that Dr. Deray's statement "stops short" of a conclusion regarding DPT causation. *See Kelley*, 68 Fed. Cl. 84, 99.

In summary, review of the record in this case results in the conclusion that much of what has been stated adverse to Dr. Tornatore's testimony cannot be sustained. Petitioners have presented a medical theory causally connecting Enrique's vaccination on October 31, 1995 with the seizures which commenced the next day on November 1, 1995. An acceptable temporal relationship has been established between the vaccination and the injury. The question of a logical sequence of cause and effect showing that the vaccination was the reason for the injury is a matter of dispute between the expert opinion expressed by Dr. Tornatore and Dr. Herskowitz's testimony that Enrique's clinical picture does not match that to be expected from Dr. Tornatore's postulated series of events following administration of the whole-cell pertussis on October 31, 1995.

In *Capizzano*, 440 F.3d at 1326, it is stated that "[t]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect

^{4/} While not specifically using the "differential" term, Dr. Tornatore's testimony at Tr. 102-10 (Nov. 3, 2006) also illustrates this standard technique in support of his opinion as to causation. Slip op. at 23.

show[s] that the vaccination was the reason for the injury.” This would certainly be the case with respect to the various tests which were performed during Enrique’s seizure treatment, such as the brain SPECT scan on November 14, 1995, which Dr. Tornatore testified supports causation (slip op. at 22) and Dr. Herskowitz testified to the contrary (slip op. at 30), although also testifying that he was not qualified to comment on the relationship between the scan and MRI tests within the same time frame. (Tr. 215-16 (Nov. 3, 2006).)

In weighing the evidence to determine whether the level of preponderance was reached which would place the burden on respondent to establish an alternative causation, also by a preponderance standard, the successor special master has subtracted weight from petitioners’ evidence on grounds that cannot be sustained upon review of the record. A reevaluation is required. Additional evidence may well be needed.

In view of the circumstances discussed it is **ORDERED**:

(1) This case is remanded to the special master for further action. *See Walther v. Sec’y of Health and Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007).

(2) The issue of whether petitioners have established, by a preponderance of the evidence, on the record as a whole, that the seizures initially occurring on November 1, 1995, and thereafter, were caused by the DPT vaccination administered to Enrique on October 31, 1995, shall be reconsidered and a new opinion rendered—the successor special master correctly sets forth the applicable standards to be applied in resolving this issue. Slip op. at 36.

(3) The proceedings on reconsideration shall be addressed to the testimony and evidence relevant to causation-in-fact, without reference to the several issues in the August 29, 2007 Slip Opinion which, on review, have not been sustained;

(4) The record on remand can include additional evidence from prior witnesses, especially if credibility issues are involved. However, to the extent possible, testimony of Enrique’s treating physicians should be obtained. Such evidence with respect to the medical records involved, Enrique’s clinical picture with reference to the conflict in the experts’ testimony, and the logical sequence of cause and effect with regard to the vaccination and Enrique’s seizures would be of assistance in

establishing whether it is more likely than not that the seizures were caused by the vaccination, by some other event, or that causation is unknown. Explanation as to efforts to establish causation and potential causes considered and rejected can be detailed. In particular, the testimony of Drs. Resnick and Deray should be most helpful in resolving this issue in a manner to further the administration of justice.^{5/}

s/ James F. Merow

James F. Merow

Senior Judge

^{5/} An examination of all reported Vaccine Act decisions in which Dr. Tornatore testified shows that his testimony has always been presented by petitioners whereas the same examination for Dr. Herskowitz shows that his testimony has always been presented for respondent. In the instant case, Dr. Herskowitz testified why he participates in the Vaccine Program. (Tr. 168-69 (Nov. 3, 2006).) Expert witnesses may well have perspectives on vaccines and causation which may not be present with treating physicians.